DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

July 22, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97 - 52

Terrance O. Noble
President
Apothecary Products, Inc.
11531 Rupp Drive
Burnsville, Minnesota 55337

Dear Mr. Noble:

During an inspection of your drug repackaging operation in Burnsville, MN, on June 25, 1997, an Investigator from the Food and Drug Administration (FDA) found your firm to be operating under significant deviations from current Good Manufacturing Practice (CGMP) regulations for drug products [Title 21, Code of Federal Regulation, Parts 210 and 211 (21 CFR 210 and 211)].

Aspirin, acetaminophen, and pseudoephedrine hydrochloride are drugs within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act). Your aspirin, acetaminophen, pseudoephedrine hydrochloride are adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the controls used for the manufacture, processing, packaging or holding of the products are not in conformance with CGMP regulations, 21 CFR 210 and 211, as documented by the investigator.

1. Packaging/production records specifically associated with a batch of drug product are not maintained for at least one year after the expiration date of the batch or three years after distribution of the batch (21 CFR 211.180).

2. There are no dated and signed master production and control records for each drug product which is to include a description of the drug product packaging materials and a specimen of the label (21 CFR 211.186).

3. There are no written procedures for the identification of drug products with a lot or control number that permits determination of the history of the manufacture and control of the batch [21 CFR 211.130 (c)].

4. There are no written procedures for the inspection of the packaging and labeling areas to assure that all drug products have been removed from previous operations and to assure that packaging and labeling materials not suitable for subsequent operations have been removed [21 CFR 211.139 (e)].

5. There are no written procedures which cover the receipt, identification, storage, handling, sampling, examination and/or testing of labeling and packaging material [21 CFR 211.122(a)].

6. There are no written procedures for controlling the issuance of labeling [21 CFR 211.125 (f)].

This letter is not meant to be all inclusive. The inspection focused on the operations relating to your recall of EZY-DOSE Convenience Packs of the above drug products. It is your responsibility to ensure adherence to each requirement of the Act and regulations relating to these and all other regulated products. Conformance with the Act and regulations could prevent recalls in the future. Failure to comply with all the requirements of the Act may result in enforcement action including seizure and/or injunction without further notice.

Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

We request that you advise us in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations. If

corrective action cannot be completed within the requested time-frame, you must promptly inform this office of the reason for the delay and the time when each violation will be corrected.

Your reply should be addressed to Acting Compliance Officer Rhonda L. Mecl at the address indicated on the letterhead. Ms. Mecl may be reached at (612) 334-4100 x 159.

Sincerely,

Edwin S. Dee
Acting Director
Minneapolis District

RLM/ccl